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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

BARNHART, LORA ELIZABETH

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 11/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/755,392

Applicant(s)

OTTO, ROEL

Examiner

Lora E Barnhart

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 6/15/04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Specification

Applicant is reminded of the proper content of an abstract of the disclosure.

A patent abstract is a concise statement of the technical disclosure of the patent and should include that which is new in the art to which the invention pertains. If the patent is of a basic nature, the entire technical disclosure may be new in the art, and the abstract should be directed to the entire disclosure. If the patent is in the nature of an improvement in an old apparatus, process, product, or composition, the abstract should include the technical disclosure of the improvement. In certain patents, particularly those for compounds and compositions, wherein the process for making and/or the use thereof are not obvious, the abstract should set forth a process for making and/or use thereof. If the new technical disclosure involves modifications or alternatives, the abstract should mention by way of example the preferred modification or alternative.

The abstract **should not refer to purported merits** or speculative applications of the invention and should not compare the invention with the prior art.

Where applicable, the abstract should include the following:

- (1) if a machine or apparatus, its organization and operation;
- (2) if an article, its method of making;
- (3) if a chemical compound, its identity and use;
- (4) if a mixture, its ingredients;
- (5) if a process, the steps.**

Extensive mechanical and design details of apparatus should not be given.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. **The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided.** The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and **should not repeat information given in the title. It should avoid using phrases which can be implied**, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

The use of the trademark "GELRITE" has been noted in this application (p.9, line 7, e.g.). It should be capitalized wherever it appears and be accompanied by the generic terminology. The trademark "APPLIKON" (p.13, line 9) should be amended similarly.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner that might adversely affect their validity as trademarks.

The disclosure is objected to because of the following informalities: Tables 1, 2 and 3 are illegible. New tables should be provided in which the top row can be clearly read. Additionally, the use of the term "minimal medium" is queried in table 3 and on p.16, for example, as applicants claim the use of a chemically defined minimal medium (p.16, line 4) but also disclose the addition of yeast extract to said medium (p.16, line 7). Applicant should clarify whether the bacteria of the invention produce lactic acid when grown only in chemically defined minimal medium, or whether addition of yeast extract is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 7-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites a "process for the preparation of lactic acid and/or lactate wherein a pentose-containing substrate is homolactically fermented by a moderately thermophilic *Bacillus* species, which ferments anaerobically." It is not clear to which element of the claim the phrase "which ferments anaerobically" refers. The claim may be interpreted to mean that the claimed process of homolactic fermentation is carried out under anaerobic conditions, or that the claimed moderately thermophilic *Bacillus* species has the capability to ferment anaerobically, but the particular process being claimed does not require anaerobic conditions.

Claim 8 recites "moderately thermophilic *bacillus*" in line 2. Scientific (Latin) names of organisms should be italicized, and the first letter of the genus only should be capitalized, e.g. *Bacillus coagulans*.

Claim 7 depends from claim 1 and recites the limitation "the fermentation broth" in lines 2-3. There is insufficient antecedent basis for this limitation in the claim. Claim 1 does not recite a fermentation broth. Claims 9 and 10 depend from claim 8 and recite the limitation "the fermentation broth" in lines 2 and 3, respectively. There is insufficient antecedent basis for this limitation in the claims. Claim 8 does not recite a fermentation broth.

Claim 9 depends from claim 8 and recites the limitation "the separation" in line 2. There is insufficient antecedent basis for this limitation in the claim. Claim 8 does not recite a separation.

Claim Rejections - 35 USC § 102

It is noted that in claims 1-10, Applicant recites the phrase "containing," which is open-claim language. It is held "the transitional phrases "comprising", "consisting essentially of" and "consisting of" define the scope of a claim with respect to what unrecited additional components or steps, if any, are excluded from the scope of the claim. The transitional term "comprising", which is synonymous with "including," "containing," or "characterized by," is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. See, e.g., *Invitrogen Corp. v. Biocrest Mfg., L.P.*, 327 F.3d 1364, 1368, 66 USPQ2d 1631, 1634 (Fed. Cir. 2003). "The transition "comprising" in a method claim indicates that the claim is open-ended and allows for additional step" (MPEP § 2111.03 [R-2] Transitional Phrases). For purposes of examination, the word "containing" is interpreted to mean "comprising."

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Payot et al. (Applicant's IDS of 6/15/04) in light of Godshall et al. (2002, AVH Association, 9th Symposium; p.23-30). The claims are drawn to a process for homolactically fermenting lactic acid or lactate using a moderately thermophilic *Bacillus* species from a pentose-containing substrate (which contains glucose, xylose, or arabinose in some dependent claims). In some dependent claims, the bacteria are

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Bacillus coagulans or *Bacillus smithii*. In some dependent claims, the lactic acid and the bacteria are separated from the vessel in which fermentation occurs. The phrase "which ferment anaerobically" in claim 1 is interpreted to refer to the bacteria themselves, not the process of fermentation.

Payot et al. teach a process for the production of lactic acid by *Bacillus coagulans* from molasses. Godshall et al. is cited as evidence that molasses comprises glucose, xylose, and arabinose (Table 3). In the process of Payot et al., the *B. coagulans* biomass is separated from the culture medium comprising fermented lactic acid (Figure 8). Additionally in the method of Payot et al., lactic acid is separated from the other components of said culture medium using high-performance liquid chromatography (p.192, column 2, paragraph 1).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-5 and 7-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over PCT '601 (2003; reference [N]) in view of Payot et al. (IDS). The claims are drawn to a process for homolactically fermenting lactic acid or lactate using a moderately thermophilic *Bacillus* species from a pentose-containing substrate (which contains glucose, xylose, or arabinose in some dependent claims). In some dependent claims, the bacteria are *Bacillus coagulans* or *Bacillus smithii*. In some dependent claims, the lactic acid and the bacteria are separated from the vessel in which fermentation occurs. The phrase "which ferment anaerobically" in claim 1 is interpreted to refer to the process of fermentation itself, not to the bacteria.

PCT '601 teaches a process for using *B. coagulans* J44 and *B. smithii* J30 to ferment lactic acid from a chemically defined medium (i.e. containing only salts, vitamins, buffers and amino acids in addition to a chosen carbohydrate source, said sources including glucose, xylose and arabinose, inter alia) in microaerophilic conditions (p.7-10). PCT '601 further teaches that said lactic acid is the majority product of said fermentation (Table 1). PCT '601 does not specifically teach said fermentation under anaerobic conditions, nor does it teach separation steps for the biomass or the produced lactic acid.

Payot et al. teach that at a given pH, the production of lactic acid by *B. coagulans* increases significantly (Table 5). Additionally, in the process of Payot et al., the *B. coagulans* biomass is separated from the culture medium comprising fermented lactic acid (Figure 8). Later in this process, lactic acid is separated from the other components

of said culture medium using high-performance liquid chromatography (p.192, column 2, paragraph 1).

One of ordinary skill in the art would have had a reasonable expectation of success in making said substitutions because it is known that *B. coagulans* ferments pentose sugars to lactic acid under anaerobic conditions, and because it is well known in the art to separate fermentation products from the culture medium for later applications.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to substitute the anaerobic conditions and separation steps of Payot et al. into the lactic acid production of PCT '601 because *B. coagulans* produces more lactic acid under said conditions. Additionally, it is industrially desirable not only to produce optically pure lactic acid, but also to collect it for later applications. The skilled artisan would have been motivated to make said modifications because efficient production and collection of lactic acid from new sugar sources, e.g. pentoses, would increase the amount of lactic acid able to be produced from carbon sources like molasses that previously could not be utilized fully.

Thus, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made.

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over PCT '601 and Payot et al. as applied to claims 1-5 and 7-9 above, and further in view of U.S. '477 (1978, reference [B]). Claim 6 is drawn to a process as described above in which lactic acid is fermented by a mixture of bacteria comprising a *Bacillus* species and another

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lactic acid-producing microorganism. PCT '601 does not teach fermentation by a mixture of bacteria.

U.S. '477 teaches a process for preparing a *Bacillus* fermentation product, using a mixture of *Bacillus natto* and other lactic acid-producing bacteria, e.g. *Lactobacillus sporogenus*, *Lactobacillus acidophilus* and *Pedicoccus acidilactici* (Example and Table 1). Accordingly, one of ordinary skill in the art would have had a reasonable expectation of success in combining two or more strains of lactic acid-producing bacteria to ferment a given carbon source because it is well known that different strains have different properties that may complement each other.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to conduct the fermentation of PCT '601 using a mixture of different fermenting bacteria because said mixture may have different properties than any of its individual components. The skilled artisan would have been motivated to make said modification because one strain may be more efficient at fermenting xylose, for example, while another is more efficient at fermenting glucose.

Thus, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over PCT '601 and Payot et al. as applied to claims 1-5 and 7-9 above, and further in view of U.S. '881 (1991, reference [A]). Claim 10 is drawn to a process as described above in which lactic acid is produced by bacteria and purified after separation from the culture medium. PCT '601 does not specifically teach additional purification steps.

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U.S. '881 teaches a process for fermenting organic acids, e.g. lactic acid, from *Bacillus coagulans* in which the bacteria are separated from the chemically defined culture medium (Example II) before the lactic acid is removed from said medium by ultrafiltration. The lactic acid is further purified using reverse osmosis (Example I).

Accordingly, one of ordinary skill in the art would have had a reasonable expectation of success in removing impurities from lactic acid produced by *Bacillus coagulans* using reverse osmosis because reverse osmosis is a technique well known in the art for purifying aqueous solutions comprising salts and sugars.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to purify the lactic acid of PCT '601 and Payot et al. with the reverse osmosis step of U.S. '881 because lactic acid produced by bacteria in culture media is contaminated with other biochemical products. The skilled artisan would have been motivated to make said modification because removing impurities from lactic acid is essential before said lactic acid can be used for downstream applications.

Thus, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lora E Barnhart whose telephone number is 571-272-1928. The examiner can normally be reached on Monday-Friday, 8:00am - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G Wityshyn can be reached on 571-272-0926. The fax phone

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number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lora E Barnhart



IRENE MARY
PRIMARY EXAMINER